

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of

Applicants : Victor A. Raul et al.
Serial No. : 10/576,991
Filed : March 6, 2007
Title : **CONTROLLED-RELEASE COMPOSITION FOR TOPICAL APPLICATION AND A METHOD OF DELIVERING AN ACTIVE AGENT TO A SUBSTRATE**
Docket : DOC 0170 PA (40218.354)
Art Unit : 1627
Examiner : S. Pihonak
Confirm. No. : 5824

EFS Web Electronic Submission

September 8, 2010

MAIL STOP PRE-APPEAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Applicants request review of the final rejection mailed May 10, 2010, in the above-identified application. No amendments are being filed with this Request. This Request is being filed with a Notice of Appeal and a Request for a one-month extension of time in which to respond to the final rejection. Review is requested for the reasons stated below.

The present status of claims is: claims 1-41 are pending. Of these, claims 8, 13, and 18-41 stand withdrawn from consideration. Claims 1-7, 9-12, and 14-18 stand rejected under 35 USC §103 as unpatentable over Kosal, U.S. Patent No. 6,545,086 in view of Gray et al., U.S. Patent No. 6,040,307, and further in view of Ulrich, U.S. Patent No. 6,365,146. Applicants filed a Response to Office Action (Final Rejection) on July 6, 2010. In the Advisory Action mailed July 27, 2010, the Examiner entered the Response, but maintained the rejection of claims 1-7, 9-12, and 14-18.

Applicants submit that the rejection is not well taken in that: clear errors of fact have been made; and clear deficiencies in the references omit one or more essential elements of the claimed invention needed to establish a prima facie case. Applicants will discuss each deficiency in the rejection in turn.

Errors of Fact and Law

In the Final Rejection, pages 2-3, the Examiner asserted that,

Kosal teaches a volatile silicon [sic, silicone] fluid; while it is acknowledged that some silicone fluids are lipophilic, there are others that are non-lipophilic. Kosal broadly teaches the presence of a silicone fluid; therefore, as there are silicone fluids which are non-lipophilic, Kosal still renders the claimed invention obvious, as Kosal teaches the claimed oil-in-water emulsion comprised [of] the elected silicone component, a surfactant, and water.

Initially, the Examiner has failed to establish a factual basis for her assertion that there are volatile silicone fluids that are non-lipophilic. The volatile silicone fluids of Kosal are certainly lipophilic. See, col. 3, lines 44-55, (the volatile silicone fluids are liquids); col. 3, lines 60-65 and Examples, esp. Examples 2-4 at col. 6, lines 58-62 (the volatile silicone fluids dilute/dissolve/solute the silicone PSA's); and col. 4, lines 24-28 (the volatile silicone fluids, blended with the silicone PSA's form the oil phase of the emulsion). Kosal provides no examples of volatile silicone liquids which are non-lipophilic, and neither has the Examiner. Kosal excludes only *non-silicone* lipophilic solvents (see, col. 3, lines 60-65), not all lipophilic solvents. To the contrary, Kosal teaches the necessity of using the volatile silicone liquids when forming the emulsion. These factual deficiencies undermines the basis of the rejection.

The Examiner also erred as a matter of logic, as Kosal does not "broadly" teach the presence of volatile silicone fluids that can be either lipophilic or non-lipophilic. All of the volatile silicone fluids taught by Kosal are lipophilic and must be lipophilic as they function to dissolve/solute the silicone PSA component of the emulsion. There is absolutely no teaching in Kosal that there is such a thing as a non-lipophilic volatile silicone fluid, let alone that such a compound could be substituted for the lipophilic silicone fluids used therein. As the disperse silicone phase of Kosal is the oil phase of the emulsion, one would not (and probably could not) use a non-lipophilic solvent in the oil phase to dissolve/solute the silicone PSA's. This error in logic also undermines the factual basis of the rejection.

As previously argued, Kosal's *silence* concerning non-lipophilic solvents also cannot form the factual basis to support a conclusion of obviousness. *In re Burt*, 148 USPQ 548, 553

(CCPA 1966) ("Silence in a reference is hardly a proper substitute for an adequate disclosure of facts from which a conclusion of obviousness may justifiably follow.")

Finally, the Examiner's legal conclusion that Kosal "teaches" the claimed oil-in-water emulsion is flawed in that the oil phase contains the volatile silicone fluid which was used to dissolve/solvate the silicone PSA. The Examiner's implication that Kosal's pressure sensitive silicone adhesive and volatile silicone liquid together make up the recited "silicone component," still ignores that fact that the volatile silicone liquid is necessary to form the emulsion and that its presence means that Kosal's emulsion is *not* "substantially free of lipophilic solvent" as claimed. Kosal's oil-in-water emulsion does contain a lipophilic solvent -- namely, the volatile silicone fluid. Thus, Kosal does not "teach" the claimed composition.

Clear deficiencies in the references omit one or more essential elements of the claimed invention needed to establish a prima facie case.

Gray and Ulrich are applied in the rejection for only limited purposes. Gray is alleged to teach the topical administration of a fungicide active agent, and Ulrich is alleged to teach that surfactants "are commonly used for drug delivery." Neither Gray nor Ulrich teach or suggest an oil-in-water emulsion that is substantially free of lipophilic solvents as claimed. Thus, the secondary references do not aid the Examiner in establishing this necessary factual support for the rejection. As discussed in detail above, Kosal also does not teach or suggest this recited element of the claims. Accordingly, as there are clear deficiencies in all of the applied references as they fail to teach a recited claim element, the rejection is not factually supported and no prima facie case for obviousness has been established.

Conclusion

For all of the above reasons, applicants submit that the rejection is not well taken, is based on factual and/or legal errors and omissions, and should be withdrawn.

Respectfully submitted,
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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) DOC 0170 PA/40218.354
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	First Named Inventor Victor A. Raul, et al.	
	Art Unit 1627	Examiner S. Pihonak

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

- applicant/inventor.
- assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)
- attorney or agent of record.
Registration number 29,001.
- attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____.

/Timothy W. Hagan/

Signature

Timothy W. Hagan

Typed or printed name

937-449-6400

Telephone number

September 8, 2010

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
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